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10/056,136	01/24/2002	Nobuyuki Tatsumi	NGB-12930	2328

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EXAMINER	
GORDON, BRIAN R	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,136	TATSUMI, NOBUYUKI	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11-23-04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3, 4-5, 7-8, 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 7, 13-17* is/are rejected.

7)☒ Claim(s) *4 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1-24-02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Response to Arguments

2. Applicant's arguments filed November 23, 2004 have been fully considered but they are not persuasive. As to the 112 rejection of claim 4, applicant has amended the claim to recite the automatic analyzer is a component in an instrument. The claim still does not further limit the automatic analyzer claimed in claim 1. Claim four does not add any additional structure to the automatic analyzer. It appears as if applicant is attempting to a claim another apparatus which incorporates the automatic analyzer. However, the claim as drafted is directed to the automatic analyzer. Furthermore, the claim does not specify the instrumentation.

Applicant has amended the independent claims to require a non-noble base metal. HyperDictionary.com defines noble metal as "any metal that is resistant to corrosion or oxidation". As such, stainless steel would be considered a noble metal. However, applicant disclosure specifies the use of stainless steel as a base metal. In view of such, the examiner asserts a prior art teaching of stainless steel coated as taught by applicant meets the limitations of the claim.

On page 9-10, applicant asserts none of the references can be construed as disclosing an automatic sampler comprising a plurality of sample vessels, and a needle

for collection liquid samples sequentially from the sample vessels. As to the "for" phrase, it expresses the intended use or function of the needle.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

The functional recitation that the needle is for collection liquid samples sequentially from the sample vessels has not been given patentable weight because it is in narrative form. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. In re Fuller, 1929 C.D. 172; 388 O.F.279.

It has been held that performing a function is not a positive limitation but only requires the ability to so perform. The examiner asserts the automated analyzer of El-Hage et al. has the ability for the needle to sequentially collect liquid from vessels 14.

Applicant further asserts none of the references disclose an automatic sampler in combination with a needle containing a non-noble base metal" and having an inner surface and an outer surface where the outer surface is "coated with a coating material that has a chemical activity lower than a chemical activity of the base metal of said needle." The examiner respectfully disagrees. El-Hage teaches Conduit 26 and rod 30 are made of a relatively inert material so that they do not chemically react with sample and reagent liquids. The inert material is preferably stainless steel or gold-coated copper" (column 4, lines 6-12). While applicant has specified the outer surface as being coated. El-Hage implicates all surfaces of a copper (non-noble metal) are coated with gold (noble metal) to avoid reactions between the surface (inner and outer surfaces) and the samples and reagents that contact the needle surfaces.

As to the amended claim 11 and new claims 14-17, as previously stated the claims require the same limitations of the automatic sampler of the base claim and fail to add structure to the claimed automated sampler. The claims appear to be an effort to claim another apparatus or instrument in which the automatic analyzer is a component thereof. It appears as if claims 14 and 16 should be amended as to recite "an instrument comprising the automatic analyzer according to claim 1 or 3, a liquid analysis....." Claims 15 and 17 should be amended to read "the instrument according to claim..." However, as presently drafted only the structure of the automated sampler is consider.

Smith does not disclose an automated sampler comprising a plurality of vessels as such the 102(b) rejection has been withdrawn.

Hoskins discloses and automated chemical analyzer comprising a transfer device or gold-plated stainless steel tube 300. Gold plating is commonly known as a coating process in which an article, in this case tubes, is dipped into a coating material and electrical charges are employed to apply the coating to the article. It is inherent that the inner and outer surface of the tube would be coated when dipped into the coating. As such the previous rejection as based upon Hoskins is hereby maintained.

In view of applicants, arguments/amendment the 102 (e) rejection of claims 1-2, 6, 11-12 as based upon King et al. is hereby withdrawn.

In view of applicants, arguments/amendment the 102(e) rejection of claims 1-2, 6, 11-12 as based upon Hutchens et al. is hereby withdrawn.

As to Li et al. the reference discloses a needle comprising stainless steel cannula. Li further discloses an alternative to deliver the voltage through a metallic coating, such as gold, deposited on the exterior of only the terminal portion of each capillary tube, where it contacts the liquid in the well (column 9, lines 31-44).

Claim Interpretation

3. Claim 4 recites "a quartz thin film that is formed on said needle by a chemical vapor deposition method." The method by which the quartz is placed on the needle does not further limit the structure of the device. As such, an equivalent device comprising a quartz coating placed thereon by different process would meet the limitations of the claim. The coating material of claim 1 has been specified as being on the outer surface, it has not been specified that the material is on the interior surface as well. Claim 4 is further interpreted as limiting the needle to having the same coating as specified in claim 1 on the interior surface of needle plus an additional quartz thin film on the interior surface.

Claim Objections

4. Claims 11 and 14-17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As to the amended claim 11 and new claims 14-17, as previously stated the claims require the same limitations of the automatic sampler of the base claim and fail to add structure to the claimed automated sampler.

5. Claims 1 and 13 objected to because of the following informalities: The claims are essentially duplicate claims. The only recited difference is claim 1 specifies how the coating material is applied to the needle. The method by which the coating is applied does not add any patentable weight to the structure of the device. Therefore both claims merely recite the option of the coating containing gold. Furthermore plating and deposited have essentially meaning. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 5, 11, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by El-Hage et al. US 5,843,378.

El-Hage et al. teaches aspirating and dispensing probes are often used to transfer liquids between various vessels (plurality of vessel) and compartments in a chemical analyzer. The liquids typically include samples to be tested and reagents for testing the samples.

The probe successively aspirates reagents from reagent vessels and transfers the reagents to the reaction cuvette. After the sample-reagent mixture incubates in the reaction cuvette, the probe transfers the reaction products to an analysis chamber (liquid analysis apparatus).

A preferred embodiment of the invention is illustrated in FIGS. 1-9. FIG. 1 shows a probe 10 for dispensing and aspirating liquid into and out of a vessel 14. Vessel 14 is held in a rack 16 which is mounted on a carousel. Probe 10 is attached to a probe positioning device, such as a mechanical arm 12. Arm 12 is designed to position probe 10 in an appropriate vessel for aspirating or dispensing liquid. Such mechanical arms for positioning probes are well known in the art.

FIG. 2 shows a cross sectional view of probe 10 (needle) and a portion of arm 12. Probe 10 includes an electrically insulative tube 18, an electrically conductive fluid conduit 26, and an electrically conductive rod 30. Conduit 26 and rod 30 are made of a relatively inert material so that they do not chemically react with sample and reagent liquids. The inert material is preferably stainless steel or gold-coated copper.

A washing station (rinsing means) is typically provided to wash the probe between aspirations of different substances.

8. Claims 1, 5, 11, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoskins et al. US 3,883,305.

Hoskins discloses an automatic chemical analysis apparatus having separate closed-looped conveyors for sample and reactant containers (plurality of vessels). At a

fixed location, sample portions from a given sample are transferred to a serial sequence of reactant containers.

The pipette is shown in greater detail in FIG. 7 and comprises a gold-plated stainless steel tube 300 of 2 mm outside diameter provided with a bore. The outer diameter tapers to 1 mm within a brass cylindrical member 301 of 5 mm diameter and 5.5 mm length which encompasses said tube 300.

9. Claims 3 and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al. US 6,132,582.

A sample handling system in a multi-channel capillary electrophoresis apparatus is disclosed. The sample handling system includes a work surface for supporting a plurality of samples located at a plurality of work surface coordinates (plurality of vessels) and a sample loading assembly comprising a plurality of loading wells. At least one of the loading wells includes a capillary fixedly positioned therein. The system further includes a programmable sample transfer device for automatically transferring a sample from a work surface coordinate to a loading well.

The material used to fabricate the pipette (needle) will depend upon the requirements of a particular application. Factors to be considered include wetability, rigidity and conductivity. Where the sample is a liquid, the wetability of the pipette should be such that sample may be introduced into the pipette in a controlled and reproducible manner. When the pipettes are passively loaded with sample using capillary action, generally the pipette should be wetable by the sample material. It is preferable that the pipette be rigid in order to facilitate location of the inlet end of the

pipette with respect to the robot arm. Finally, where an electrical measurement is used in the tip sensor, the pipette should be electrically conductive. Preferred pipette materials include but are not limited to stainless steel, platinum and gold coated materials, glass, fused silica, and plastic or plastic coated materials, e.g., stainless steel coated with a parylene (synthetic resin).

10. Claims 1, 5, 11, and 13-15, are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. by US 6,365,024.

Li et al. discloses an automated electrophoretic system is disclosed. The system employs a capillary cartridge having a plurality of capillary tubes. The cartridge has a first array of capillary ends projecting from one side of a plate. The first array of capillary ends are spaced apart in substantially the same manner as the wells of a microtitre tray of standard size (plurality of vessels). This allows one to simultaneously perform capillary electrophoresis on samples present in each of the wells of the tray.

The separation process employs a capillary tube filled with conductive gel. To introduce the sample, one end of the tube is placed into the DNA reaction vial. After a small amount of sample enters the capillary end, both capillary ends are then placed in separate buffer solutions. A voltage potential is then applied across the capillary tube. The voltage drop causes the DNA sample to migrate from one end of the capillary to the other.

FIG. 3A shows a needle 140 used in forming a tube assembly 160 which can then be directly inserted into a mounting plate 162, as shown in FIG. 3B. The needle 140 comprises a metallic cannula 142. In the preferred embodiment, the cannula 142 is

formed from stainless steel having an inner diameter of 0.064 in. and an outer diameter of 0.072 in. The cannula 142 is provided with a bevel 144 at the end which is dipped into a well.

As is known to those skilled in the art, the voltage differential may be delivered to the first capillary ends through other means as well. For instance, instead of contacting a common plate to which the needles are connected, voltage leads may be connected directly to each needle. Alternatively, individual leads may be dipped into the liquid in each well. Another alternative is to deliver the voltage through a metallic coating, such as gold, deposited on the exterior of only the terminal portion of each capillary tube, where it contacts the liquid in the well. Also, the voltage may be delivered directly to the wells through one or more leads, as described earlier. One skilled in the art can readily formulate alternative approaches to delivering a voltage to the first capillary end.

11. Claim 3 and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Safir et al. US 6,475,391.

Safir et al. discloses a method is disclosed for characterizing a plurality of non-biological polymer samples. The method includes the steps of injecting four or more non-biological polymer samples into a mobile-phase of a liquid chromatography system, chromatographically separating at least one sample component or polymer molecule of each of the four or more injected polymer samples from other sample components or polymer molecules thereof in a chromatographic column, and serially detecting a property of the four or more non-biological polymer samples or of components or

polymer molecules thereof with a flow-through detector at an average sample throughput of not more than about 10 minutes per sample (abstract).

Automated sampling equipment is available commercially for introducing multiple samples into liquid flow systems in a serial manner. While such commercially-available auto-sampling equipment could be used with this invention, currently available systems have several drawbacks. First, commercially available auto-samplers typically operate with a single predefined rack or tray configuration, which contains vials in a rectangular, linear, or rotary array.

As such, aspects of this invention are directed to an auto-sampler and auto-sampling methods. In a preferred embodiment, with reference to FIG. 4, an auto-sampler 200 can comprise a movable probe (tip) 201, typically mounted on a support arm 203, a translation station 221 for providing three-dimensional motion of the probe, and a microprocessor 222 for controlling three-dimensional motion of the probe between various spatial addresses. The auto-sampler 200 preferably also comprises a user-interface (not shown) to allow for user programming of the microprocessor 222 with respect to probe motion and manipulations. The probe 201 can have an interior surface defining a sample-cavity and an inlet port for fluid communication between the sample cavity and a polymer sample 20 (in a plruarlity of vessels; see Figs 7A-B).

A programmable XYZ robotic arm (RSP 9651, Cavro Scientific Instruments, Inc., Sunnyvale, Calif.) mounted on a platform was fitted with a fluoropolymer-coated (synthetic resin) steel needle probe (Cavro part # 722470), a piston syringe pump

(Cavro, model XL 3000) connected to the needle probe by flexible fluoropolymer tubing, and a fluoropolymer probe wash/waste station was mounted on the platform.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over et al. as applied to claim 5 above, and further in view of Sohrab US 6,793,632.

EL-Hage et al., Hoskins et al., or Li et al., specify that the resin coating is polyetheretherketone (PEEK).

Sohrab discloses a device for sampling at least one biological fluid constituent and measuring at least one target constituent within the biological fluid.

To be able to withstand a sterilization process the micro-needles and/or the array of micro-needles may be formed of or coated with an insulating material, such as a ceramic, glass, silica, polymer, plastics and the like. Examples of polymers are polyacrylates, epoxies, polyesters polyetheretherketone, liquid crystalline polyesters, or their composites.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of EL-Hage et al., Hoskins et al., or Li et al by coating it PEEK material in order to ensure the integrity of the needle is maintained throughout a sterilization process.

Allowable Subject Matter

16. Claims 4 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach nor fairly suggest a needle having an outer surface coated with a coating material that includes a noble metal including platinum, a platinum

group metal, or gold and interior surface coated with the same outer coating in addition to a thin film of quartz and a needle containing a non-noble base metal that includes nickel or chromium.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Roesicke, Holt et al., Wittmer et al., and Moreno et al. disclose fluid transfer devices.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

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